

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
JOHN B. HARDAWAY, III
NEXSEN PRUET ADAMS KLEEMEIER LLC
P.O. BOX 10107
GREENVILLE, SC 29603

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 32483-05	Date of Mailing (day/month/year) 13 FEB 2006
International application No. PCT/US04/38044	International filing date (day/month/year) 15 November 2004 (15.11.2004)
Applicant DIGITALDERM, INC	

1. ☒ The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34, chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90 *bis*.1 and 90 *bis*.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer YOSEF KASSA Telephone No. 571 2727452
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Form PCT/ISA/220 (April 2002)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 32483-05	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/US04/38044	International filing date (<i>day/month/year</i>) 15 November 2004 (15.11.2004)	(Earliest) Priority Date (<i>day/month/year</i>) 13 November 2003 (13.11.2003)
Applicant DIGITALDERM, INC		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 10 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box No. II)

3. ☐ Unity of invention is lacking (See Box No. III)

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☐ the text is approved as submitted by the applicant.
☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

a. the figure of the drawings to be published with the abstract is Figure No. 1

- ☐ as suggested by the applicant.
 ✕ ☒ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.

b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/38044

Box IV TEXT OF THE ABSTRACT (Continuation of Item 5 of the first sheet)

NEW ABSTRACT

A software-based image management system for use in dermatological examination of a patient's skin (22) for cutaneous melanoma is carried on a compact disk together with images of all portions of the skin (28). Images can be navigated quickly and easily by moving from low-through medium- to high-resolution image, adjusting the images for best veiwing using various controls and scrolling ((30).

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/38044

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : G 06 K 9/00

US CL : 382/118,128, 130

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 382/118,128, 130

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US (KILLCOMMONS et al) 23 July 2002, col. 13, lines 52-67.	5, 11, 12
Y	US 6,251,073 A (IMRAN et al) 26 June 2001, col. 12, lines 40-67.	1-20
Y	US 5,291,889 A (KENET et al) 08 March 1994, col. 2, lines 1-44.	1-20
A	US 6,006,126 (COSMAN) 21 Dec. 1999, all columns.	1-20
A	US 6,088,137 (TOMIZAWA) 11 July 2000, all columns.	1-20
A	US 6,152,881 (RAINES et al) 28 Nov. 2000, all columns.	1-20

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&"

document member of the same patent family

Date of the actual completion of the international search

27 November 2005 (27.11.2005)

Date of mailing of the international search report

13 FEB 2006

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US

Commissioner for Patents

P.O. Box 1450

Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Authorized officer

Yosef Kassa

Telephone No. 571-272-7452

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
JOHN B. HARDAWAY, III
NEXSEN PRUET ADAMS KLEEMEIER LLC
P.O. BOX 10107
GREENVILLE, SC 29603

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 32483-05		Date of mailing (day/month/year) 13 FEB 2006 FOR FURTHER ACTION See paragraph 2 below
International application No. PCT/US04/38044	International filing date (day/month/year) 15 November 2004 (15.11.2004)	Priority date (day/month/year) 13 November 2003 (13.11.2003)
International Patent Classification (IPC) or both national classification and IPC IPC(7): G 06 K 9/00 and US Cl.: 382/118, 128, 130		
Applicant DIGITALDERM, INC		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 27 November 2005 (27.11.2005)	Authorized officer Yosef Kassa Telephone No. 571 272-7452
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/US04/38044

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/38044

Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 1-20 YES

Claims NONE NO

Inventive step (IS)

Claims NONE YES

Claims 1-20 NO

Industrial applicability (IA)

Claims 1-20 YES

Claims NONE NO

2. Citations and explanations:

Claims 1-4, 6-10 and 13-20 lack an inventive step under PCT Article 33(3) as being obvious over Kenet et al (U.S. Patent 5,291,889), and further in view of Imran et al (U.S. Patent 6,251,073).

With regard to claim 1, Kenet discloses plural digital images showing the skin of a patient (see col. 4, lines 1-24); and a software application (computer system) adapted for managing said plural digital images by facilitating viewing said plural digital images (see col. 4, lines 19-24) in a range of resolutions (manipulation and enhancement of the image) and in a sequence (reads on image frame), said plural digital images (see Fig. 3, item 36).

Kenet does not explicitly call for software application being carried on portable memory storage device. However, in the same field of endeavor, Imran teaches this feature (see col. 12, lines 63-67). At the time of the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate the teaching of Imran portable memory storage device into Kenet system. The suggestion/motivation for doing so would have been to store image data into a portable memory storage device (see col. 12, lines 63-67). Therefore, it would have been obvious to combine Imran with Kenet to obtain the invention as specified in claim 1.

With regard to claim 2, Kenet is silent about wherein said portable memory storage device is a compact disk. However, in the same field of endeavor, Imran teaches this feature (see col. 12, lines 63-67). At the time of the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate the teaching of Imran portable memory storage device into Kenet system. The suggestion/motivation for doing so would have been to store image data into a portable memory storage device (see col. 12, lines 63-67). Therefore, it would have been obvious to combine Imran with Kenet to obtain the invention as specified in claim 2.

With regard to claim 3, Kenet discloses wherein said each digital image has at least six million pixels (see col. 4, lines 22-27).

With regard to claim 4, Kenet discloses wherein said plural digital images include plural sets of digital images, each set of said plural sets of digital images showing the skin of said patient, and wherein said software application is further adapted to permit comparison of said plural sets of digital images so that a user can look for changes over time in moles present on the skin (see col. 4, lines 1-26).

With regard to claim 6, Kenet discloses a memory adapted to store plural digital images showing the skin of a patient (see col. 4, lines 28-32); and a software application in communication with said memory and adapted to retrieve digital images from said plural digital images when said plural digital images are stored in said memory (see col. 4, lines 19-24), said software application having a graphical user interface that enables a user to view said plural digital images (see col. 4, lines 25-27), means for displaying said plural digital images in a range of magnifications (see col. 2, lines 39-43), means for selecting portions of said plural digital images for display (see col. 2, lines 23-26), and means for annotating said plural digital images when said plural digital images are stored in said memory (see col. 2, line 32-38).

With regard to claim 7, Kenet discloses wherein said software application permits comparison of images of said plural digital images (see col. 4, lines 27-32).

With regard to claim 8, Kenet discloses wherein said software application is adapted to receive annotations to images of said plural digital image (see col. 2, lines 32-38).

With regard to claim 9, Kenet discloses wherein said software application is adapted to display said plural digital images with annotations (see col. 4, lines 19-24).

With regard to claim 10, Kenet discloses wherein said software application includes means for acquiring additional digital images and adding said additional images to said memory (see col. 4, lines 19-24).

With regard to claim 13, Kenet discloses wherein said memory is dimensioned to hold at least one set of 33 digital images, each image of said 33 images containing at least six million pixels (see col. 4, lines 19-26).

Claim 14 is similarly analyzed and rejected the same as claims 1 and 6.

With regard to claim 15, Kenet discloses further comprising the steps of: making a second set of plural digital images of the skin of said patient, images of said second set corresponding to images of said second set to define image pairs; storing said second set of plural digital images in said digital memory device; and comparing said first set to said second set of digital images to determine if there are changes in moles present on the skin of said patient (see col. 4, lines 28-32).

With regard to claim 16, Kenet discloses wherein said comparing step further comprises the step of comparing image pairs side by side (see col. 4, lines 28-32).

With regard to claim 17, Kenet discloses wherein said comparing step further comprises the step of comparing corresponding image pairs by overlaying said images of said first set with images of said second set (see col. 4, lines 46-50).

With regard to claim 18, Kenet discloses wherein said making step further comprising the step of making each digital image substantially normal to the skin of said patient (see col. 3, lines 30-39).

Claim 19 is similarly analyzed and rejected the same as claim 13.

With regard to claim 20, the step of installing a software application on said digital memory device, said software application having a graphical user interface and being adapted for managing said first set of plural digital images (see col. 4, lines 19-27).

2. Claims 5, 11 and 12 lack an inventive step under PCT Article 33(3) as being obvious over Kenet et al (U.S. Patent 5,291,889) and Imran et al (U.S. Patent 6,251,073), and further in view of Killcommons et al (U.S. Patent 6,251,073).

With regard to claim 5, Kenet and Imran are silent about wherein said range of magnification is up to 3200%. However, in the same field of endeavor, Killcommons teaches this feature (see col. 13, lines 64-67). At the time of the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate the teaching of Killcommons image magnification process into Kenet system. The suggestion/motivation for doing so would have been to provide the process of selecting percentage of zooming (see col. 13, lines 59-67). Therefore, it would have been obvious to combine Killcommons with Kenet to obtain the invention as specified in claim 5.

With regard to claim 11, Kenet and Imran are silent about wherein said software application includes means for encrypting said plural digital images. However, in the same field of endeavor, Killcommons teaches this feature (see col. 4, lines 5-9). At the time of the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate the teaching of Killcommons image magnification process into Kenet system. The suggestion/motivation for doing so would have been to provide the process of selecting percentage of zooming (see col. 13, lines 59-67).

With regard to claim 12, Kenet and Imran are silent about means for reversing said plural digital images so that a user can see said plural digital images as if in a mirror. However, in the same field of endeavor, Killcommons teaches this feature (see col. 14, lines 56-63). At the time of the invention was made, it would have been obvious to a person of ordinary skill in the art to incorporate the teaching of Killcommons image magnification process into Kenet system. The suggestion/motivation for doing so would have been to provide the process of selecting percentage of zooming (see col. 13, lines 59-67).

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the *PCT Applicant's Guide*, a publication of WIPO.

In these Notes, "Article," "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended ?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Preliminary Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When ? Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments ?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.